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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,716	11/13/2001	Yun-Hwa Peggy Hsieh	35721/239475(5721-17)	6335

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EXAMINER	
MOHAMED, ABDEL A	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 02/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/007,716	HSIEH, YUN-HWA PEGGY	
	Examiner	Art Unit	
	Abdel A. Mohamed	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

ACKNOWLEDGMENT TO IDS AND STATUS OF THE CLAIMS

1. The information disclosure statement (IDS) and Form PTO-1449 filed 4/5/02 are acknowledged, entered and considered. Claims 1-16 are present for examination.

OBJECTION TO THE SPECIFICATION, CLAIMS AND ABSTRACT

2. The specification, claims and abstract are objected in the recitation"RTA01/2104334v1" and "AttyDktNo. 35721/239475 (5721-17)" at the end corner of each page of the specification, claims and abstract. Deletion of the above file locator from the disclosure of the specification, claims and abstract would obviate this objection.

CLAIMS REJECTION-35 U.S.C. § 112 2nd PARGRAPH

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 1-14 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in the recitation "substantially homogenous" because it is unclear as to how much the type II-like collagen is homogenous. Amendment of the claim to recite the limitation of claim 4 or claim 5 or claim 6 or incorporating the limitations as defined on page 7, lines 13-22 in the instant specification is suggested.

Claims 7 and 11 recite the limitation "said salt" in step b), line 3. There is insufficient antecedent basis for this limitation in the claim 7 or claim 11.

Claims 8 and 9 recite the limitation "said salt solution" in line 1. There is insufficient antecedent basis for this limitation in claim 7 or claim 8 or claim 9.

Claims 12 and 14 are indefinite and vague in the recitation "comprising administering...." because it is not clear to what kind of administration the claims refer. If it is intended for oral or parenteral or intradermal or other means of administration, the mode or route of administration should be recited in the claims (e.g., administering orally or intravenously or subcutaneously, etc.) is suggested.

Claim 16 is improper composition claim because the claim comprises only one ingredient, namely type II-like collagen. For composition claim to be proper, the claim should recite more than one component or ingredient. Appropriate correction is required.

Claim 16 is indefinite in the recitation "substantially free of natural contaminants" because it is unclear as to how much the type II-like collagen is free of natural contaminants. Appropriate clarification is required.

CLAIMS REJECTION-35 U.S.C. § 102(b)

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Weiner et al. (U. S. Patent No. 5,843,445).

Claim 15 is directed to a pharmaceutical composition comprising type II-like collagen and a pharmaceutically acceptable carrier and claim 16 is directed to a composition that comprises type II-like collagen that is substantially free of natural contaminants. Similarly, Weiner et al. discloses a pharmaceutical formulations comprising type II collagen for the treatment of autoimmune arthritis of animals including humans. Since the pharmaceutical formulation of type II collagen is administered by oral, enteral or by-inhalation to humans for treatment of rheumatoid arthritis, said pharmaceutical formulation has to be free of all contaminants including natural contaminants. (See e.g. the title, abstract, summary of the invention and the claims, particularly claims 1, 2, 6-8, 11, 12 and 15-25) as directed to claims 15 and 16. Thus, the prior art discloses the invention substantially as claimed, and as such, anticipates claims 15 and 16 as drafted.

CLAIM REJECTIONS-35 U.S.C. § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weimer et al. (U.S. Patent No. 5,843,445) taken with Wolfinbarger (U.S. Patent No. 5,714,582) and Neff et al. (U.S. Patent No. 5,925,736)

The primary reference of Weimer et al. teaches as discussed above a pharmaceutical formulations comprising type II collagen and its fragments and analogs thereof wherein the type II collagen is from chicken or bovine and a therapeutically effective amount is administered for the treatment of autoimmune arthritis of animals including humans. Since the pharmaceutical formulation of type II collagen is administered by oral, enteral or by-inhalation to humans for treatment of rheumatoid arthritis, said pharmaceutical formulation has to be free of all contaminants including natural contaminants. (See e.g. the title, abstract, summary of the invention and claims 1-25) as directed to claims 12-16.

The reference of Weimer et al. differs from claims 1-16 in not teaching the extraction and use of type II-like collagen isolated from jellyfish species for treating arthritis such as rheumatoid arthritis. Although, Applicant acknowledges on page 2,

lines 23-28 and page 3, lines 22 to page 4, lines 26 in the instant specification that type II collagen from chicken and cows has been used to treat rheumatoid arthritis (RA) and induce immune tolerance. On page 7, lines 9-12 in the instant specification, Applicant defines by stating that "type II-like collagen" is intended collagen with characteristics similar to those of type II collagen of mammals, such as the molecular mobility, salting-out concentration, high content of hydroxylysine, solubility properties, absence of disulfide bonds, and highly hygroscopic nature of the protein. Further, Applicant acknowledges that methods for extraction of collagen (type I-V) from jellyfish are known in the art (See e.g., page 7, lines 29 to page 8, lines 11). The secondary reference of Wolfinbarger discloses the isolation and characterization of the mesogloea collagen of a primitive animal, the jellyfish *Stomolophus nomurai*, belonging to the class *Scyophozoa* in the *Coelenterata*. The jellyfish type V collagen was isolated, prepared, and purified similarly like the instantly claimed invention by the steps of extracting the collagen with dilute acid, precipitating the collagen with salt, then the precipitated salt fraction of said collagen resolubilized at pHs 3-9, preferably between 6 and 7.52 pH by sequentially increasing the molarity of salt from precipitated collagen from about 0.5 M to 4.0 M, preferably 1.0 M to 3.8 M and removing said precipitated collagen fraction after each sequential increase, and thereby collecting the collagen fraction precipitated at 3.5 M salt (See e.g., col. 3, lines 10 to col. 4, lines 66) as directed to claims 1, 2, 7, 10 and 11. The salt solution comprises alkali metal halides, e.g., NaCl (See e.g., col. 5, lines 19-20) as directed to claims 8 and 9. The reference discloses that the jellyfish comprises one or more elements selected from the group consisting of the mantle, tentacles and the

whole organism, and wherein said collagen comprises 0.25 to 95 wt % of collagen protein (See e.g., claims 4 and 5 of the reference) as directed to claims 3-5 of the instant invention. Thus, the reference teaches the production of invertebrate type V collagen, in particular from jellyfish of class *Scyophozoa* in the *Coelenterata* by extracting collagen in dilute acid and then precipitating it by a salt solution. The precipitated collagen resolubilized, collected and formulated as pharmaceutical composition to be used in a variety of medical and dental applications.

Furthermore, the reference of Neff et al. teaches methods and compositions for the treatment of arthritis, in particular rheumatoid arthritis. The compositions comprise one or more different types of collagen or collagen derivatives. Specific combinations of collagen and/or collagen derivatives may be used to treat arthritis, in particular rheumatoid arthritis. The collagen(s) and/or collagen(s) derivatives used in the subject compositions may be either obtained from natural sources or produced recombinantly (See e.g. summary of the invention). On cols. 3-5, the prior art describes the relationship of 18 types of naturally occurring collagens by their structures and their biological functions. Further, on col. 7 and Table I, the reference shows collagen types such as Type II and Type V that are used to treat arthritis e.g., rheumatoid arthritis. Although, type II that is naturally occurring or recombinantly produced is preferably used (See e.g., Examples disclosed on cols. 13 and 14) in the treatment of rheumatoid arthritis, hence, clearly showing that both types (i.e., types II and V) are useful in the treatment of arthritis. Thus, in view of this, the selection of the appropriate types of collagen would have been optimization of the art recognizable variation because the

secondary references of Wolfinbarger teaches the isolation and extraction of jellyfish type V collagen isolated from the same source with the same or substantially the same method as the claimed jellyfish type II collagen and the reference of Neff et al. shows the relationships of various collagens in the treatment of rheumatoid arthritis, particularly, the relationship between type II and type V collagens.

Thus, one of ordinary skill in the art would have been motivated at the time the invention was made to apply the teachings of the secondary reference of Wolfinbarger (i.e., isolation, extraction and purification of invertebrate type V collagen) and Neff et al. teachings of using various collagen e.g., types II and V to treat arthritis to the primary reference of Weiner et al. use of type II collagen from chicken and cows to treat rheumatoid arthritis and induce immune tolerance thereof because such features of using various collagens to treat arthritis are known or suggested in the art, as seen in the secondary reference, and including such features of using type II-like collagen isolated from jellyfish species into the method of the primary reference would have been obvious to one of ordinary skill in the art to obtain the known and recognized functions and advantages thereof.

Therefore, the combined teachings of the prior art makes obvious the claimed invention's collagen composition of type II-like collagen isolated from jellyfish species, method for extracting the composition thereof, and method for treating arthritis such as rheumatoid arthritis by administering a pharmaceutical formulation thereof so as to induce immune tolerance, absent of sufficient objective factual evidence or unexpected results to the contrary.

CONCLUSION AND FUTURE CORRESPONDENCE

6. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed number is (571) 272-0955. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The appropriate fax phone number for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196

Christopher S. F. Low

Mohamed/AAM

CHRISTOPHER S. F. LOW
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February 20, 2004